K002148

AUG 22 2000

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd
Indianapolis IN 46250
(317) 576 3723

Contact person: Priscilla A Hamill

Date prepared: July 14, 2000

Predicate device

The modified device is substantially equivalent to the ELECSYS® HCG Test System cleared under K961487.

Device Name

Proprietary name: ELECSYS® HCG Test System

Common name: HCG Test

Classification name: System, Test, Human Chorionic Gonadotropin

Device description

The ELECSYS® HCG Test System is a two step sandwich immunoassay with streptavidin microparticles and electrochemiluminescence detection.

Results are determined using a calibration curve that is generated specifically on each instrument by a 2-point calibration and a master curve provided with the reagent bar code.

510(k) Summary, continued

Intended use	For the quantitative determination of the sum of human chorionic gonadotropin (hCG) in human serum and plasma.
Indication for use	The Elecsys® HCG Test System is indicated for the early detection of pregnancy.
Comparison of modified and predicate device.	The Elecsys® HCG Test reagent differs from the predicate device in the following ways: • Modification of antibody concentrations, and • Addition of components to minimize HAMA interference. Performance characteristics of the modified device have been evaluated and do not differ significantly from the original device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

AUG 22 2000

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Priscilla A. Hamill
Regulatory Affairs, Laboratory Systems
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K002148
Trade Name: Roche Diagnostics ELECSYS® HCG Test System
Regulatory Class: II
Product Code: DHA
Dated: July 14, 2000
Received: July 17, 2000

Dear Ms. Hamill:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): N/A

Device Name: **ELECSYS® HCG Test System**

Indications For Use: **For the in vitro quantitative determination of the sum of human chorionic gonadotropin (hCG) in human serum and plasma. The Elecsys® HCG Test System is intended for use in the early detection of pregnancy.**

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K002146

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)